K103623 1/2

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newdeal®
An Integra LifeSciences Company

510(k) SUMMARY

Newdeal® Interphalangeal implant

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Date summary was prepared: March 12, 2012

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Name of the device:

Propriety Name:	Newdeal® Interphalangeal implant
Common Name:	Pin, Fixation, Smooth
Classification Name: (21CFR 888.3040)	Smooth or threaded metallic bone fixation fastener
Device Product Code:	HTY
Classification Panel:	Orthopedic

Substantial Equivalence:

The Newdeal Interphalangeal implant is substantially equivalent to the commercially marketed devices, Newdeal® K-Wire, (K022599), Memometal Intramedulary Bone Fastener (K070598) and Merete Medical MetaToe EndoSorb Hammer Toe Pin (K100414).

Device description:

The Newdeal Interphalangeal implant is designed to respect anatomical flexion to achieve fixation of interphalangeal arthrodesis of the lesser toes in case of:

- Fixed or semi-fixed hammer toe
- Revision of failed arthrodesis or arthroplasty
- Shortening due to length excess of the second toe

This interphalangeal implant configuration will be offered in two different sizes.

Indications for Use:

The **Newdeal® Interphalangeal implant** is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes.

Examples include:

- rigid or semi-rigid hammertoe deformity
- revision of failed arthroplasty or arthrodesis
- 2nd toe shortening

Testing and Test Results:

Static and Fatigue Bending tests were performed comparing the mechanical properties of Newdeal K-wire (K022599) and the Merete Medical MetaToe EndoSorb Hammer Toe Pin (K100414) to the Newdeal Interphalangeal Implant. Results from both analyses helped to support substantial equivalence. Clinical data were also provided to support equivalence.

Conclusion:

The Newdeal® Interphalangeal implant is substantially equivalent to the commercially marketed devices, Newdeal K-Wire (K022599), Memometal Intramedulary Bone Fastener (K070598) and Merete Medical MetaToe EndoSorb Hammer Toe Pin (K100414).

The proposed device does not change the intended use or fundamental scientific technology of the predicate devices, and does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Newdeal SAS
% Ms. Marilyse Latour
Immeuble Séquoïa 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest - FRANCE

MAR 2 0 2012

Re: K103623
Trade/Device Name: Newdeal Interphalangeal Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: March 12, 2012
Received: March 13, 2012

Dear Ms. Latour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
MEP Acting Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103623

Device Name: **Newdeal Interphalangeal Implant**

Indications For Use:

The **Newdeal Interphalangeal Implant** is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes.

Examples include:

- rigid or semi-rigid hammertoe deformity
- revision of failed arthroplasty or arthrodesis
- 2nd toe shortening

Prescription Use ___X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103623